REMARKS

Claim Objections

Claim 1 was rejected because it contained a typographical error. Claim 1 has been amended to correct that error.

In view of the amendment to claim 1, it is requested that the claim objection be withdrawn.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1-15 and 25-26 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 and 25-26 were objected to because of the use of the abbreviation HPC2 without identifying to which HPC2 they refer. Claims 4-9 and 26 have been canceled. The HPC2 language in the remaining claims has been deleted and these claims now refer to SEQ ID NO: 2.

Claims 1-7 and 9-15 were objected to because the recitation "a modified form which is functionally equivalent" was unclear. Claims 4-7 have been canceled and the remaining claims have been amended to cancel the language "a modified form which is functionally equivalent".

Claims 2 and 8-9 were objected to because the recitation of "stringent conditions" was unclear. Claims 8-9 have been canceled and Claim 2 has been amended to cancel the "stringent conditions" language.

Claims 2, 4 and 6-9 were objected to because the recitation of "corresponding RNA" was unclear. The recitation of "corresponding RNA" has been changed in Claim 2 to "complementary RNA". Claims 4 and 6-9 have been canceled.

Claims 4, 9 and 26 were objected to because the recitation of "allelic variant" was unclear. These claims have been canceled.

Claims 5-7, 9 and 26 were objected to because the recitation of "mutated form" was unclear. These claims have been canceled.

Claim 10 was objected to because the recitation of "said nucleic acid" was unclear as to whether it referred to the nucleic acid probes or the nucleic acid of claim 1. Claim 10 has been clarified as to the sentence structure.

Claim 12 was objected to because the recitation of "the coding sequence for the HPC2 polypeptide" and "said coding sequence" did not have sufficient antecedent basis. Claim 12 has been clarified as to the sentence structure.

Claim 12 was also objected to because the recitation of "capable of directing the expression" was unclear. Claim 12 has been amended by omitting "suitable control" and "capable of directing", and replacing those with "regulatory" and "which control", respectively. The meaning of the claim is clarified by changing the language (see page 27, lines 19-22).

Claim 25 was objected to because the recitation of "derived from" was unclear. Claim 25 was amended by replacing "derived from" with "13 or more nucleotides long and identical or complementary to SEQ ID NO: 1".

Claim 26 was objected to because it could not be determined if "for determination of all or part or the sequence of the HPC2 gene" and "having the nucleotide sequence set forth in SEQ ID NO:1" referred to primers of claim 25 or of claim 26. Claim 26 has been canceled.

In view of the amendments to the claims and the above arguments, it is requested that the rejection of claims 1-15, and 25-26 under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-15 and 25-26 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 10-15, and 25 have been amended and claims 4-9 and 26 have been canceled. The language in Claims 1-3, 10-15, and 25 is limited by SEQ ID NO:1, SEQ ID NO:2, or by other SEQ ID NOs and their complements and no longer includes allelic variations or mutations. Further, the specification discloses the structural features of SEQ ID NO:1 and SEQ ID NO:2. Claim 25 has been amended to refer specifically to SEQ ID NO:1, so it can no longer be read as "*any* pair of oligonucleotide primers." The claimed primers are those that are at least "13 or more nucleotides long and identical or complementary to SEQ ID NO:1."

Claims 1-15, and 25-26 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Office Action states that the claims are broadly drawn to almost any polynucleotide, provided that it has minimal correlation to the polynucleotide encoding SEQ ID NO:2. The claims have been amended so that they only encompass specific SEQ ID NOs and their complements. Further, the language which may imply mutations, alterations, modifications, variations, and alleles in a polynucleotide has been omitted from the claims. Claims 4-9 and 26 have been canceled.

As a result of the amended and canceled claims, it is requested that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections Under 35 U.S.C. § 102(a)

Claims 2, 8 and 9 were rejected under 35 U.S.C. §102(a) as being anticipated by Accession AC005277, IDS AN. Claims 8 and 9 have been canceled. Accession AC005277 is the genomic sequence of a portion of Chromosome 17. Claim 2 is drawn to an isolated nucleic acid of SEQ ID NO:1, or its complement. SEQ ID NO:1 is a cDNA whereas Accession AC005277 is a genomic DNA composed of introns and exons. No information is presented in the GENBANK disclosure indicating what portions of the sequence are introns and what are exons, how they are to be spliced together, or where start and stop codons are. It is urged that the disclosure of the genomic Accession AC005277 sequence does not anticipate the amended claim 2.

According to In re Gene R. Wilder, "a prior publication or patent description will be considered as anticipatory when its disclosure is at once specific and enabling with regard to the particular subject matter at issue ... However, such disclosure may yet be held not to legally anticipate the claimed subject matter if it is found not to be sufficiently enabling, in other words, if it does not place the subject matter of the claims within 'the possession of the public.'" 57 C.C.P.A. 1314, 1319, 429 F.2d 447, 451 (1970). Accession AC005277 was published in GENBANK without any further information about the genomic sequence. The cDNA sequence was not enabled because the only information given was that it was a genomic sequence from Chromosome 17 of humans. There was no mention of the type of genes on the chromosome or their function, thus the disclosure

of Accession AC005277 was not enabling. Further, the disclosure did not place the subject matter within the "possession of the public." The public was not able to determine the exons of the HPC2 gene that predisposed individuals to prostate cancer through the information of Accession AC005277.

In re Gene R. Wilder also states that there is "no anticipation where it has been proved that a compound apparently specifically described in a reference disclosure could not possibly have been made by the process taught by the reference." *Id* at 1320 (citing In re Jacobs, 50 C.C.P.A. 1316, 318 F.2d 743 (1963)). In the present situation, the disclosure did not teach a process to make the applicant's present invention.

In view of the amendments to the claims and the above arguments, it is requested that the rejection of claim 2 under 35 U.S.C. §102(a) be withdrawn.

Rejections Under 35 U.S.C. § 102(b)

Claim 25 was rejected under 35 U.S.C. §102(b) as being anticipated by Ohagi et al. The technique taught in Ohagi is for primer pairs of human PC2 found on Chromosome 20. Claim 25 has been amended to encompass a pair of oligonucleotide primers but with the limitation that the primer pairs must determine a nucleotide sequence of SEQ ID NO: 1, which is the Human Prostate Cancer predisposing gene found on Chromosome 17. Claim 25, as amended, specifically identifies SEQ ID NO: 1, which is the HPC2 gene of Chromosome 17, as being the nucleotide sequence to which the primers will be complementary or identical.

In view of the amendment of Claim 25 clarifying the *HPC2* gene and the arguments mentioned above, it is requested that the rejection of claim 25 under 35 U.S.C. §102(b) be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 2, 8, 9 and 25-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Accession AC005277, IDS AN. Claims 8, 9, and 26 have been canceled. Claim 2 has been amended to delete reference to any nucleic acid which can hybridize to SEQ ID NO:1 thereby narrowing the claim to require a nucleic acid comprising SEQ ID NO:1. The nucleic acid of

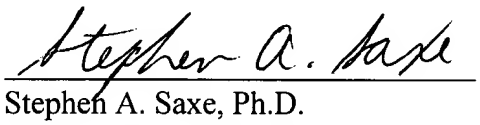
Accession AC005277 does not teach SEQ ID NO:1. Claim 25 has also been amended so that it refers specifically to SEQ ID NO:1. As a result, Claim 25 is narrowed to a pair of primers identical to or complementary to SEQ ID NO:1.

The Office Action mentions that although Accession AC005277 fails to teach a primer pair, use of a primer pair would be an obvious variation of the invention, thus making Claims 2 and 25-26 unpatentable under 35 U.S.C. §103(a). The applicant respectfully disagrees. Accession AC005277 does not make Claims 2 and 25-26 unpatentable under 35 U.S.C. §103(a) because there was a lack of motivation for combining the polynucleotide of Accession AC005277 and primer pairs. According to Ruiz v. A.B. Chance Co., the "motivation to combine may be found explicitly or implicitly" in the teachings within the references. 234 F.3d 654, 665 (Fed. Cir. 2000). In addition, "whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness of making the combination" is a question that must be asked before declaring a claim invalid due to obviousness. Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1371 (Fed. Cir. 2000). In the case of Accession AC005277, there was no motivation to combine the nucleic acid and the primer pairs. Further, there was nothing in Accession AC005277 that suggested the desire to combine the nucleic acid and primer pairs. Prior to the instant disclosure, all that was taught by Accession AC005277 was a genomic sequence with no indication whether or where a gene was encoded. In order to invalidate a claim due to obviousness, "sufficient motivation [must be shown] for one of ordinary skill in the art *at the time of invention*." Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1344 (Fed. Cir. 2000) (emphasis added). In order for there to be obviousness the motivation to combine primer pairs had to exist prior to the present invention. The "best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references." Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1371 (Fed. Cir. 2000). Hindsight may deem that primer pairs and Accession AC005277 could have been combined, but the motivation must exist at the time of the invention rather than later.

In view of the amendments to the claims and the above arguments, it is requested that the rejection of claims 2, 8, 9, and 25-26 under 35 U.S.C. §103(a) be withdrawn.

In view of the above amendments and remarks, it is believed that the present application meets the requirements of the patent statutes and is patentable over the prior art. Reconsideration of the application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned in order to expedite the prosecution of this application.

Respectfully submitted,



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Amended Claim 1: Version with markings to show changes made

1 (amended). An isolated nucleic acid coding for [an HPC2 polypeptide, said] a polypeptide [comprisingg] comprising the amino acid sequence set forth in SEQ ID NO:2 [or a modified form which is functionally equivalent] or a complement of said nucleic acid.

Amended Claim 2: Version with markings to show changes made

2 (amended). The isolated nucleic acid of claim 1 wherein said [DNA has] nucleic acid comprises the nucleotide sequence (a) set forth in SEQ ID NO:1, or (b) its complement[, (c) a corresponding RNA or (d) a nucleotide sequence which hybridizes under stringent conditions to the nucleotide sequence of (a), (b) or (c)].

Amended Claim 3: Version with markings to show changes made

3 (amended). The isolated nucleic acid of claim 1 wherein said [DNA has] nucleic acid comprises the nucleotide sequence set forth in (a) SEQ ID NO:3, (b) SEQ ID NO:28, or (c) complements thereof.

Amended Claim 10: Version with markings to show changes made

10 (amended). A set of nucleic acid probes for use in a microchip assay wherein each of said nucleic acid probes comprises at least 8 contiguous nucleotides of a nucleic acid as claimed in claim 1 and said set encompasses part or all of said nucleic acid as claimed in claim 1.

Amended Claim 12: Version with markings to show changes made

12 (amended). An expression vector which comprises an isolated nucleic acid of claim 1 wherein [the coding sequence for the HPC2 polypeptide or modified form thereof] said nucleic acid is operably linked to [suitable control] regulatory sequences [capable of directing] which control expression of said [coding sequence] nucleic acid in host cells for said vector.

Amended Claim 14: Version with markings to show changes made

14 (amended). A method of producing a polypeptide [which is the HPC2 polypeptide of claim 1] of SEQ ID NO:2 which comprises (i) culturing [the] host cells containing an expression vector encoding said polypeptide under conditions suitable for the production of said [HPC2] polypeptide and (ii) recovering said polypeptide.

Amended Claim 15: Version with markings to show changes made

15 (amended). A method as claimed in claim 14 which further comprises labeling the [recovered] polypeptide which is recovered.

Amended Claim 25: Version with markings to show changes made

25 (amended). A pair of single-stranded oligonucleotide primers for determination of a nucleotide sequence of [a *HPC2* gene] SEQ ID NO: 1 by a nucleic acid amplification reaction, the sequence of said primers being 13 or more nucleotides long and identical or complementary to SEQ ID NO:1 [derived from genomic clones for *HPC2*, and the use of said primers in a nucleic acid amplification reaction resulting in the synthesis of DNA or RNA corresponding to all or part of the sequence of the *HPC2* gene].